

§ 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

(a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25, (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993–0002.

(b) As specified in § 807.22(b)(1) and (b)(3), all owners or operators shall update their establishment registration and device listings annually during the period beginning on October 1 and ending on December 31 of each fiscal year.

(c) Failure to submit any of the required information on time, as specified in § 807.22(a) and (b), will put the establishment in a “failed to register” or “failed to list” status as applicable.

The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until the required information is submitted to and processed by FDA.

[77 FR 45943, Aug. 2, 2012]

§ 807.35 Notification of registrant.

(a) The Food and Drug Administration will assign each device establishment a registration number after verifying the initial establishment registration information that has been submitted. The owner or operator of the establishment will also be assigned an identifying number. Both numbers will be sent to the official correspondent by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(b) Owners or operators of device establishments who also manufacture or process biological products (including devices licensed under section 351 of the Public Health Service Act) or drug products at the same establishment

must also register and list those products under part 607 or part 207 of this chapter, as appropriate. Registration and listing for human blood and blood products, devices licensed under section 351 of the Public Health Service Act, and licensed biological products used in the manufacture of a device licensed under section 351 of the Public Health Service Act, are subject to part 607 of this chapter; registration and listing for all other drug products (including other biological products that are also regulated as drug products) are subject to part 207 of this chapter.

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

[69 FR 11312, Mar. 10, 2004, as amended at 77 FR 45943, Aug. 2, 2012]

§ 807.37 Public availability of establishment registration and device listing information.

(a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA Web site, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the Internet should be directed to the Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993–0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.